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10/725,890	12/02/2003	Steven E. Walak	1001.1632101	3380

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EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/725,890	WALAK, STEVEN E.	
	Examiner	Art Unit	
	BRADLEY J. OSINSKI	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,25-57,59-70 and 73-78* is/are pending in the application.

4a) Of the above claim(s) *28-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,25-27,57,59-70 and 73-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-9, 11, 13, 15, 16, 18, 19-21, 25-26, 57, 59, 61, 63-64, 66-68, 73, 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ren et al (US 6,045,547), and further in view of Viera (US 6,039,699).

a. Regarding claim 1, Ren et al teaches a catheter shaft with an inner and outer layer with varying stiffness along the length of the catheter. Specifically taught by Ren et al is, “One catheter tube section has a first, inner layer formed of a flexible material and a second, outer layer formed of a stiffer material.” (Abstract). Also taught is, “The outer tube can have a region of substantially constant wall thickness followed distally by a taper which terminates, leaving the inner tube with no outer layer.” (Col. 2, lines 17-19) Ren et al does not, however, teach that both portions should be made of metal. Ren also teaches the device is co-extruded (title). Viera teaches a multi-layer guidewire where each the inner and outer layers are made of metal. “The first material may exhibit superelastic properties and may include an alloy having nickel and titanium. The second material may include stainless steel.” (Col. 1 lines 52-55) Those versed in the art would have reasonably recognized and appreciated that guidewires and

catheters perform nearly the same function, with the exception that guidewires often do not have lumens. Both devices are designed to be flexible and thin such that they can navigate and pass through body cavities, ducts or vessels. It would be therefore be obvious to one of ordinary skill in the art to make a catheter of Ren et al using the materials suggested by Viera, in this case metallic inner and outer layers. Referral to the **MPEP section 2113** is made, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

b. Regarding claim 2, Ren et al teaches, "The outer tube can have a region of substantially constant wall thickness followed distally by a taper which terminates, leaving the inner tube with no outer layer." (Col. 2 lines 17-19) Also see figure 1.

c. Regarding claims 3-4, Ren et al teaches, "…decreasing the thickness of the outer layer with increasing distal position. The thickness of the outer layer can be tapered down over several inches…" (Col. 1 lines 66-67 to Col. 2 lines 1-2) It is apparent from this citation that the outer layer covers a portion of the inner layer in the proximal region.

d. Regarding claims 5, 22, and 70, Ren et al teaches, "Referring now to FIG. 2, a second catheter tube section 42 is illustrated, joined distally at 44 to first

section inner layer 34. Second catheter tube section 42 includes an inner layer or tube 46 and an outer layer or tube 48." (Col. 4, lines 4-7), furthermore there is an alternative embodiment where "A smooth appearance near the junction of two joined tube sections is provided in one embodiment by abutting and bonding the tubes rather than overlapping them." (Col. 4, lines 20-23) Visualizing the alternative embodiment, it is apparent that moving distally from the proximal region of the abutted assembled tubes, a region with an outer layer would be followed by a region with no outer layer, followed immediately by a region with a second outer layer. As such the 'assembled' product of two abutted tubes of Ren et al would be structurally indistinguishable from a medical device in which a second segment of the outer layer were allowed to remain upon the inner layer of a medical device.

e. Regarding claims 6 and 7, Ren et al teaches, "One method uses an extruder having a co-extrusion head capable of…" (Col. 4 lines 62-63, emphasis added) If the catheter was produced by co-extrusion or co-drawing the products would be structurally indistinguishable from that of the current application, as such both co-extrusion and co-drawing are taken to be anticipated by Ren et al.

f. Regarding claim 8, Ren et al teaches, "The outer tube can have a region of substantially constant wall thickness followed distally by a taper which terminates, leaving the inner tube with no outer layer." (Col. 2, lines 17-19)

g. Regarding claims 9 and 10, Reference to **MPEP section 2113** is again made as grinding away or etching the outer metallic layer to expose the inner

metallic layer would result in an apparatus that is structurally indistinguishable from Ren et al.

h. Regarding claims 11 and 13, Viera teaches, "…corewire formed from a material exhibiting superelastic properties, such as a nickel-titanium or Nitinol alloy for example." (Abstract) It is art recognized and appreciated that nickel-titanium alloy and super-elastic nickel-titanium alloy are used in both catheters and guidewires when a high-flexibility but strong metal is desired. As such it would have been obvious to one of ordinary skill in the art to form the inner layer of the catheter of Ren et al with nickel-titanium alloy or super-elastic nickel-titanium alloy due to the alloys ability to withstand large amounts of deformation with a high degree flexibility.

i. Regarding claim 15, Ren et al teaches, "FIG. 1 illustrates a first catheter tube section 20 having a proximal region 22, a distal region 24, and a lumen 40 therethrough." (Col. 3 lines 3-5)

j. Regarding claim 16, Viera teaches, "The second material may include stainless steel." (Col. 1 lines 54-55) It is art recognized and appreciated that stainless steel is used in both catheters and guidewires as an outer rigid layer that covers a more flexible interior layer. As such it would have been obvious to one of ordinary skill in the art to use stainless steel as the rigid outer layer as stainless steel is both more rigid than most other flexible metals and corrosion resistant.

k. Regarding claim 18, it is apparent that Ren et al specifically teaches a catheter, "A multi-layer catheter tube… " (Abstract)

l. Regarding claims 19 and 25, Ren et al suggests a guide catheter via, "Guide catheters are often used as conduits, to guide…" (Col. 1, lines 17-18)

m. Regarding claims 20, and 21, Ren et al does not teach grinding the inner layer to provide a reduced outer diameter on the inner portion (claim 20), or a taper on the inner portion (claim 21). Viera teaches, "Corewire 320 further tapers from segment 326 along a segment 328 to distal segment 330. Segments 324, 326, and 328 may be formed to any suitable length and diameter using a suitable centerless grinding technique, for example." (Col. 2 lines 62-65) The taper and inner layer radius differences would not be easily formed by the co-extrusion method addressed by Ren et al and in some cases, depending upon the region of the body the catheter is intended to go through, a changing inner layer radius is desirable as opposed to the one taught by Ren et al. Therefore it would be obvious to one of ordinary skill in the art to grind the metallic inner portion to provide a different segment length or radius and to have a taper between regions of different radii because it would provide a method to create multiple segments with varying lengths and outer radii to better customize catheter properties such as flexibility in specific regions of the catheter.

n. Regarding claims 26 and 27, it is well known within the art that modulus of elasticity and tortional rigidity are properties that represent stiffness. On object having a higher modulus of elasticity relative to another with similar shape, it

would inherently mean that the object is more rigid. Tortional rigidity is similar, if an object had higher tortional rigidity, it would inherently be more rigid relative to another object of similar shape. It would thus have been obvious to one of ordinary skill in the art to have the modulus of elasticity and tortional rigidity of the inner metallic portion be lower than that of the outer metallic portion, because modulus of elasticity and tortional rigidity are measures of stiffness and Ren et al teaches having a stiffer outer layer compared to inner layer. (See citation in paragraph 6a above)

o. Regarding independent claims 57 and 73, see claim 1 above. Ren et al teaches, "The outer layer tapes distally, having decreasing layer thickness with increasing distal position. The decreasing wall thickness provides a decreasing stiffness contribution which imparts increasing flexibility to the catheter portions having a smaller outer layer." (Abstract). Ren et al also teaches why these properties are desirable, "Advancing a catheter along the above described path requires pushability, torqueability and flexibility in differing degrees in different regions of the catheter shaft. In particular, the proximal region of the catheter shaft will ultimately lie within the femoral artery, where flexibility is not as important as the pushability of the torqueability required to maneuver the more distal regions of the catheter disposed within the coronary arteries. (Col.1, lines 27-34) Combined with the reasons for rejecting claim 1 in paragraph 3a above, it would have been obvious to one of ordinary skill in the art to make a catheter with a lumen and inner and outer layers made of different metals with the distal

region of the inner layer exposed to provide a higher level of flexibility to the distal region relative to the proximal region and a higher level of stiffness to the proximal region relative to the distal region, in order to create a catheter with the art recognized desirable properties of pushability and torqueability in the proximal region of a catheter and maneuverability in the distal region of the catheter.

p. Claims 59 and 61 are rejected for the same reasons as established in numbered paragraphs 6h and 6n.

q. Claim 63 is rejected for the same reasons as established in numbered paragraphs 6i and 6n.

r. Claim 64 is rejected for the same reasons as established in numbered paragraphs 6j and 6n.

s. Claim 66 is rejected for the same reasons as established in numbered paragraphs 6k and 6n.

t. Claim 67 is rejected for the same reasons as established in numbered paragraphs 6l and 6n.

u. Claim 68 is rejected for the same reasons as established in numbered paragraphs 6m and 6n.

v. Regarding claims 76 and 77, Applicant discloses co-extrusion as the method via which the device is constructed with a bond along the entire length/every point of contact of the device common to both metallic portions. Co-extrusion is disclosed by Ren.

2. Claims 12, 17, 60, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over references 1 and 2 as applied to claims 1 and 57 above, and further in view of O'Brien et al (WO 99/58184).

w. Regarding claims 12 and 60, neither Ren et al nor Viera teach making the metallic inner portion of beta titanium. O'Brien et al however, which is drawn to a stent deploying apparatus teaches beta-titanium as a composite to form the medical device. Specifically taught is "…In the over-the-wire catheter of the present invention, the inner tube 134 or outer tube 136 (or both) is formed of a beta-titanium material. The beta-titanium material has a relatively low modulus of elasticity and pseudoelastic characteristics for tracking through…" (Page 15 lines 17-20). It would thus have been obvious to one of ordinary skill in the art to form the inner metallic tube from beta-titanium because beta-titanium's properties paralleling those taught as desirable by reference 1 and 2, the property of a low modulus of elasticity particularly.

x. Claims 17 and 65 are rejected for the same reasons as stipulated in numbered paragraphs 6j and 7a above.

3. Claims 14 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over references 1 and 2 as applied to claims 1 and 57 above, and further in view of Rooney et al (US 6,306,105 B1).

y. Regarding claims 14 and 62, while Viera does teach a super-elastic nickel titanium alloy as addressed in paragraph 6h above, neither Ren et al nor Viera specifically teach a linear-elastic nickel-titanium alloy inner metallic layer. Rooney

et al however teaches a guide wire similar to that taught by Viera with "…a nickel-titanium core with a stainless steel coil to provide a wire with improved kink resistance and good pushability." (Abstract) and "…core 20 may preferably be formed of a linear-elastic alloy of nickel titanium" (Col. 3 lines 37-39) It would therefore have been obvious to one of ordinary skill in the art to compose the metallic inner layer of linear-elastic nickel-titanium alloy in order to provide improved kink resistance and good pushability.

4. Claims 74, 75 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ren et al (US 6,045,547) and Viera (US 6,039,699) as applied to claim 1 above, and further in view of Jones et al (5,843,050).

z. Regarding claims 74, 75 and 78, while Ren substantially discloses the apparatus as claimed, it does not disclose a helix or spiral pattern on the shaft. However, Jones discloses spiral cuts in a catheter modify the flexibility of the catheter (abstract, Col.2 lines 44-46). it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a spiral pattern with the device of Ren as taught by Jones as it is a known method of modifying the flexibility of a catheter.

Response to Arguments

5. Applicant's arguments filed 3/25/2010 have been fully considered but they are not persuasive. The claims are still product by process claims, meaning that the steps of the actual method itself need not be taught so long as the product is indistinguishable. Ren (the primary reference) teaches co-extruding the layers together; while it is drawn

to plastics instead of metals, co-extrusion has been suggested as a means for joining the layers together. Product by process claims were created to describe products that resisted explanation by other categories. Applicant's arguments are most applicable to claims that fall under process of making. Since these are product-by-process claims, the Examiner takes the position that a product formed by co-extruding the layers together is taught by Ren and Viera suggests specific alternative materials such as metals. That neither reference does not teach a specific method of how that co-extrusion occurs does not render the rejection non-applicable to the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767